



Sarah E. Johnston, Partner  
2029 Century Park East, Suite 300  
Los Angeles, CA 90067-2904  
Tel (310) 284-3880  
Fax (310) 284-3894  
Sarah.Johnston@btlaw.com

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**VIA ECF**

The Honorable Denise L. Cote  
United States District Court Judge  
Southern District of New York  
500 Pearl Street, Room 1910  
New York, New York 10007

***In Re: Acetaminophen ASD/ADHD Prods. Liab. Litig., 1:22-md-3043 (DLC)***  
**JJCI's Letter Regarding FDA Engagement and Request to File Under Seal**

Dear Judge Cote,

Defendant Johnson & Johnson Consumer Inc. (JJCI) writes to apprise the Court regarding its ongoing engagement with FDA. The Parties previously filed two Joint Letters regarding the same on November 30, 2022 (DE 218) and December 16, 2022 (DE 274). In the December 16 Letter, JJCI advised the Court that it intended to serve a subpoena duces tecum on FDA seeking targeted documents related to FDA's consideration and disposition of the potential risks of in utero exposure to acetaminophen, as alleged by Plaintiffs in this litigation.

On or about December 21, 2022, JJCI served the aforementioned subpoena on FDA. Following the close of business on Friday, January 27, 2023, JJCI received an initial production of documents from FDA in response to that subpoena. This production was made by the Center for Drug Evaluation and Research pursuant to the Protective Order entered in this action (DE 351), as indicated in the accompanying transmittal correspondence from FDA. Given that this production was made pursuant to the MDL Protective Order, we respectfully request permission to file the FDA production under seal, and maintain this initial treatment of the FDA production until we receive further clarification regarding dissemination of these documents.

We note that FDA has made certain redactions to the documents. As informed by FDA, these redactions were made to protect pre-decisional advice, opinions, and recommendations of agency employees.

It is JJCI's understanding that FDA will produce the remaining responsive documents by the end of February. We will continue to update the Court and the Parties regarding JJCI's continued engagement with FDA, and welcome the opportunity to discuss that engagement with the Court and the Parties at the Court's convenience.

Respectfully submitted,

/s/ Sarah E. Johnston